

# The Transparency Revolution in PhRMA Pricing<sup>1</sup>

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## **ABSTRACT:**

Rube Goldberg would have struggled to create a pharmaceutical pricing system so characterized by conflicts of interest, information disparities, and pricing opacity. These factors enable drug companies to price discriminate on a global scale, capturing billions of dollars of consumer surplus. Recent developments have made Canadian and other foreign drug prices more visible to US consumers and policymakers, threatening the system of price discrimination. If the industry clings to its ways, all may be swept away in US price controls. Greater transparency would yield significant health benefits and may stave off government rate setting.

## **I Conflicts of Interest**

Conflicts of interest are pervasive in the prescription pharmaceutical market, affecting intermediaries such as physicians, payors, and pharmacy benefit managers (PBMs), as well as researchers, policymakers, and patient advocacy groups. The extent to which potential conflicts of interest have become actualized is generally hidden from view, often in data controlled by PhRMA members.

- **Physicians**

Prescription laws place the physician and other prescribers between the consumer and the manufacturer. Drug marketing historically targets the prescriber to increase sales.<sup>2</sup> This marketing includes many tangible and intangible benefits conferred on prescribers by drug company detailers. Conflicts of interest may damage health to the extent prescribing patterns are influenced by these benefits from drug companies.<sup>3</sup>

- **Payors**

Third-party payment isolates the patient from the full cost of the drug. The moral hazards of third-party payment are well known: isolation from the acquisition cost induces additional utilization. Co-pays and deductibles reduce but do not eliminate this effect. A substantial expansion of pharmaceutical third-party payment is underway. The Medicare Modernization Act of 2003 extends third-party payment to over 7.3 million seniors who had previously been self-paying and 4.7 million low-income seniors will receive a \$600 annual credit on their Medicare drug card during the transition. The CBO estimated the net increase in Medicare Part D drug reimbursements as \$507 billion over the next ten

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<sup>1</sup> This analysis focuses upon markets for patented pharmaceuticals, hence “PhRMA.” Generic prescription drugs share many similarities, but also feature distinctive market characteristics which are not discussed herein.

<sup>2</sup> Drug marketing also targets the pre-physician in academic medical centers, other prescribers, and after a 1997 rule change, consumers through direct to consumer (DTC) advertising. 62 Fed. Reg. 43171 (Aug. 12, 1997), *finalized in* 64 Fed. Reg. 43197 (Aug. 1999).

<sup>3</sup> S.L. Coyle, “Physician-Industry Relations. Part 1: Individual Physicians,” *Annals of Internal Medicine* 135, no. 5 (Mar. 5, 2002): 396-402.

years.<sup>4</sup> Subsequently released data from the CMS Office of the Actuary increased the net federal cost by an additional \$103.5 billion.<sup>5</sup> Part D is a remarkable expansion of third-party payment for pharmaceuticals, fueling moral hazards in drugs with over \$600 billion in reimbursement over the next decade.

- **PBMs**

PBMs aggregate demand from insurers, negotiate supply contracts with pharmaceutical companies, and administrate policies to change prescription utilization patterns. The consumer backlash against managed care rationing also implicates PBMs, particularly when a formulary is administered to deny or switch prescriptions. Less well known are the conflicts of interest on the supply side. Recent litigation suggests that PBMs retain substantial discounts from drug manufacturers which are not fully passed on to insurers, employers or patients. In conditions of information disparity and pricing opacity, PBMs retain the spread between the drug manufacturers and the payors. In the absence of a duty of loyalty to payors, employers or patients, PBMs are also able to receive bonuses from drug companies for meeting certain marketing targets. These payments are substantial (\$430 million in 2001 from Merck to Medco), and exert significant pressure on prescription patterns.<sup>6</sup> One settlement in 2002 requires Medco to disclose to patients the health plan's net cost of a switched drug, but Medco's own net cost remains confidential.<sup>7</sup> The Medicare Modernization Act of 2003 requires the FTC to study conflicts of interest in PBMs,<sup>8</sup> while simultaneously funneling the Part D benefit package through PBMs.<sup>9</sup>

- **Researchers**

A substantial portion of biomedical and health policy research is funded by drug companies. Most clinical trials are funded by the company which will introduce the drug. Some members of FDA review panels and senior scientists at NIH receive drug company

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<sup>4</sup> CBO, *Estimate on H.R. 1* (Congressional Budget Office, Nov. 20, 2003).

<sup>5</sup> R. Foster, Office of the Actuary, CMS, *Rough Estimates of Increase in Net Medicare and Other Federal Costs Under Selected Draft Senate Finance Proposals* (June 11, 2003); see also D. Rogers, "Fever Is Rising in Drug-Bill Imbroglio," *Wall Street Journal* (May 4, 2004): A2; S.G. Stolberg & R. Pear, "Mysterious Fax Adds to Intrigue Over the Medicare Bill's Cost," *New York Times* (Mar. 18, 2004).

<sup>6</sup> See, e.g., *United States ex rel. Hunt v. Merck-Medco Managed Care, LLC*, No. 00-CV-737 (E.D. Penn. 2004). In this case, which settled in April 2004, Massachusetts alleged that Medco retained more than half of the rebates. A. Dembner, "Medco to Pay \$5.5M in Drug Benefits Settlement," *Boston Globe* (Apr. 26, 2004): B1. CareFirst Blue Cross Blue Shield filed a similar suit, claiming that rebates were not passed on as contractually required. *Group Hospitalization and Medical Services v. Merck-Medco Managed Care, LLP*, 295 F.Supp.2d 457 (D.N.J. 2003). Other PBM cases have been consolidated in federal district court in New York, *In re Medco Health Solutions, Inc., Pharmacy Benefits Management Litigation*, 2003 WL 21303228 (Jud.Pan.Mult.Lit. Jun. 3, 2003), and in Massachusetts, *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 307 F.Supp.2d 196 (D. Mass. 2004).

<sup>7</sup> B. Martinez, "Merck Agrees to Pay \$42.5 Million to Settle Medco Benefits Case," *Wall Street Journal* (Dec. 10, 2002): D10.

<sup>8</sup> Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. 108-173 (Dec. 8, 2003) § 110.

<sup>9</sup> Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. 108-173 (Dec. 8, 2003) § 101.

funds.<sup>10</sup> Many health policy studies draw from the same funding base. A growing body of research confirms the intuition that funding influences research outcomes and publication.<sup>11</sup> Drug company funding systematically biases medicine towards particular pharmaceutical interventions. Conflicts weaken our confidence in the reported results. Evidence-based medicine requires untainted data.

- **Policymakers**

Drug companies deploy significant lobbying resources to influence public policy towards increased pharmaceutical reimbursement.<sup>12</sup> The net increase in federal spending for drugs in the Medicare Modernization Act of 2003 exceeds \$600 billion.<sup>13</sup> With so much at stake, rent-seeking behavior from regulated industries is unsurprising. Indeed, spending hundreds of millions of dollars to influence this spending might be cost effective for the industry.

- **Patient Advocacy Groups**

Less well observed have been drug company sponsorship of patient advocacy groups. Drug companies rent the legitimacy of patient advocacy groups, while the cash-strapped groups appreciate the significant funding. Conflicts of interest are created if patient advocacy groups (or their leaders) become dependent upon drug company funding and modify their message to suit their financial partners, such as promoting off-label uses.<sup>14</sup>

## **II Information Disparities**

Information disparities in pharmaceutical markets are quite simple: drug companies have the information and everyone else doesn't. Examples include profits on patented drugs; safety, efficacy and economic evaluation data; and the lack of transparent pricing.

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<sup>10</sup> National Institutes of Health, *Report of the National Institutes of Health Blue Ribbon Panel on Conflict of Interest Policies* (Draft, May 5, 2004): 1-5.

<sup>11</sup> J.E. Bekelman, Y. Li, and C.P. Gross, "Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review," *Journal of the American Medical Association* 289, no. 4 (Jan. 22, 2003): 454-465; S.S. Chopra, "Industry Funding of Clinical Trials: Benefit or Bias?," *Journal of the American Medical Association* 290(1) (July 2, 2003): 113-114.

<sup>12</sup> Public Citizen, *The Other Drug War II: Drug Companies Use an Army of 623 Lobbyists to Keep Profits Up* (June 12, 2002). This report only covers federal lobbying. Many other drug industry lobbyists are at work internationally and at state and local governments. At recent meetings of the West Virginia Drug Cost Management Council, drug industry lobbyists outnumbered the 11 Council members.

<sup>13</sup> See notes 4-5 above.

<sup>14</sup> The data is anecdotal at this point. Three recent examples may illustrate. InterMune's strategy for increasing off-label use of Actimmune included funding a patient advocacy group, the Coalition for Pulmonary Fibrosis. A. Pollack, "Suit By Former Employee Charges Promotion of Drug's Off-Label Use," *New York Times* (May 12, 2004): C1. La Jolla Pharmaceutical financially supports the Lupus Foundation of America to speed the approval of its lupus drug, Riquient. P. Crabtree, "FDA to Review S.D. Firm's Lupus Drug," *San Diego Union-Tribune* (Feb. 18, 2004): C3. In 2001, PhRMA gave \$70,000 to the Children's Health Coalition, chaired by Audrey Spolarich, a paid lobbyist for Schering-Plough in 2000. The Children's Health Coalition lobbied for the extension of the 6 month patent extension for pediatric testing. Public Citizen, *The Other Drug War II: Drug Companies Use an Army of 623 Lobbyists to Keep Profits Up* (June 12, 2002): 4-5, n. 17.

- **Pharmaceutical Innovation: Are Patent Rents Optimal?**<sup>15</sup>

Consider the important issue of pharmaceutical innovation. The *ex ante* defense of both drug patents and high US prices is innovation: absent patents and higher prices, companies will not undertake R&D. But this simple model doesn't tell us when we have enough innovation or when patent rents are optimal. At some point, pharmaceutical patent rents and R&D spending cross a threshold and become supra-optimal. (Perhaps we can all agree that supra-optimality will have been reached if 50% of GDP is spent on pharmaceutical R&D). Rather than re-stating the simple model of pharmaceutical innovation, policy makers must ask whether the present level of patent rents are above or below optimality. Perhaps the Australians have it right; maybe the US level is still too low. How would we know? What data would be needed to make this calculation? PhRMA holds the trump card of 'innovation' without allowing any dispositive data to escape. Without reliable data, PhRMA lives in the bygone eras of FFS and cost-based reimbursement.

The starting point for determining patent rent optimality must be accurate and detailed company-level information on drug R&D. The companies have this information, but policy makers don't. Information from publicly traded companies is too imprecise, unaudited for this purpose, and is contaminated by lines of business unrelated to human pharmaceutical innovation. Tax audits may reveal more detail, particularly transfer pricing audits or R&D credit audits, but taxpayer information is confidential.<sup>16</sup> PhRMA publishes R&D information from company surveys, but the stakes are too high for blind trust. It is unacceptable to base important pharmaceutical policy decisions primarily upon data supplied voluntarily by the companies themselves. Tax returns are filed under penalties of perjury and yet frequently result in audit adjustments. Merck recently announced it may owe \$2.04 billion in taxes due to a preliminary audit adjustment from the IRS.<sup>17</sup> SEC filings are not necessarily more accurate. In April 2002, Merck announced in an SEC filing that Medco had overstated its revenues by \$12.4 billion over the previous 3 years by booking as income various co-pays received by pharmacies.<sup>18</sup> Information on R&D is likely to be subject to similar pressures, particularly when not audited by the government. Nevertheless, researchers use this suspect dataset, chiefly because it is the best data available.<sup>19</sup>

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<sup>15</sup> For a more complete treatment of pharmaceutical patent rent optimality, see K. Outtersson, "Pharmaceutical Arbitrage," *Yale Journal of Health Policy, Law & Ethics* 5, no. 1 (pending, 2004).

<sup>16</sup> Once the company files to challenge the IRS assessment in federal court, many materials may enter the public record. Useful information might be obtained in a sporadic fashion by examining the public case files in recent federal tax cases involving pharmaceutical companies.

<sup>17</sup> B. Martinez, "Merck Says It May Owe the IRS Up To \$2.04 Billion on Deductions," *Wall Street Journal* (May 10, 2004): A3.

<sup>18</sup> B. Martinez, "Co-Payments to Pharmacies Lifted Drug Giant's Revenue; Firm Stands by Treatment," *Wall Street Journal* (July 8, 2002): A1.

<sup>19</sup> See, e.g., J.A. DiMasi, R.W. Hansen, & H.G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics* 22 (2003): 151-185.

Another yardstick for patent rent optimality would be the profitability of the companies. Publicly traded pharmaceutical companies are a very profitable corporate sector.<sup>20</sup> Reported data on PhRMA member profits might understate the patent rents currently obtained, for shareholders would not be the only ones to benefit from supra-optimality. An industry with supra-optimal patent rents would also be characterized by consistently above-average executive compensation, investments in barriers to entry (such as IP litigation, marketing, and acquisitions), and rent-seeking behaviors (such as lobbying). PhRMA excels in all of these areas.

Finally, we do not know how company R&D would respond to a modest reduction in profits.<sup>21</sup> It is possible that a modest reduction in profits would trigger an increase in R&D spending as firms strived for competitive advantage. Nor is increased R&D spending the singular Holy Grail of pharmaceutical policy. If pricing was differentiated based upon the relative value of the therapies – as Patricia Danzon has suggested<sup>22</sup> – then R&D could be focused on more valuable therapies, even if aggregate R&D spending declined.

- **Data on Safety, Efficacy and Economic Evaluation**

A second major information disparity is data on the safety, efficacy and economic evaluation of drugs. Companies fund the vast majority of clinical studies, and have great financial pressure to put the best plausible face on data when applying for marketing approval and subsequently in the marketing process. Allegations have been mounting recently on the ethical lapses of drug companies and their contracted researchers, but the deeper problem is that policy makers cannot know the true extent of the problem. Much of this data remains secret. Why isn't all safety and efficacy data made public? Shouldn't every drug regulatory authority see all of the data? Why not embrace complete transparency? Will the trump card of 'innovation' be played again?

Public clinical trials and economic evaluation of drugs are a possible 'third way' between price controls and price opacity. Uwe Reinhardt and others have suggested a public effort to perform head to head trials of drugs, settling the clinical arguments in the full light of day.<sup>23</sup> A complementary approach would use this data to reimburse for pharmaceutical value, also known as economic evaluation. Undertaking this research will require both transparent data and many years. One presently functioning model is the Australian Pharmacy Benefits Scheme maligned by PhRMA and attacked by the USTR in the negotiations for the Australia – US Free Trade Agreement. The USTR

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<sup>20</sup> D.H. Kreling, et al., *Prescription Drug Trends: A Chartbook Update* (The Kaiser Family Foundation, Nov. 2001): exh. 32. IRS data show high profits and low taxation, G. Guenther, *Federal Taxation of the Drug Industry from 1990 to 1996* (Congressional Research Service, Dec. 13, 1999), but tax information on individual companies is protected from disclosure.

<sup>21</sup> U.E. Reinhardt, "Perspectives on the Pharmaceutical Industry," *Health Affairs* 20, no. 5 (2001): 136-149, at 142.

<sup>22</sup> P.M. Danzon, "Pharmaceutical Benefit Management: An Alternative Approach," *Health Affairs* 19, no. 2 (2000): 24-25.

<sup>23</sup> U.E. Reinhardt, "An Information Infrastructure For The Pharmaceutical Market," *Health Affairs* 23, no. 1 (2004): 107-112.

called for increased “transparency” in the PBS process.<sup>24</sup> Requiring drug companies to publicly release the “Phase IV” PBS submissions would be a good first step.

- **Drug Marketing**

Information disparities also drive DTC advertising and drug detailing to physicians. Patients and their physicians increasingly rely on drug companies for information on pharmaceutical therapies. Armed with billions of dollars in free samples and educational support, drug detailers occupy the information vacuum to the advantage of their particular products. Some payors now sponsor academic detailers to undo some of the work of the drug company representatives, but it is an uphill struggle at best.

To the extent that drug markets are characterized by information disparities, the price elasticity for their products decreases and higher prices may be sustained. This pricing inelasticity is persistent, even after patent expiration. Neo-classical economic theory predicts that after generic entry, the brand name drug’s price should drop to a new equilibrium at the generic price. In the US market, something quite different occurs. After generic entry, some market share is lost to the generic competitor as the most price sensitive customers defect, but significant numbers of customers (patients, prescribers or payors) remain loyal, even when the company *increases* the price of the drug.<sup>25</sup>

- **Pricing Opacity**

Anyone working in pharmaceutical policy understands how difficult it is to obtain accurate, comparable pricing data.<sup>26</sup> Take a simple example: What price does the government pay for a dose of Lipitor 40mg?

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<sup>24</sup> USTR, *Free Trade ‘Down Under:’ Summary of the U.S.-Australia Free Trade Agreement* (Feb. 8, 2004): 3 (“In implementing these principles, Australia will make a number of improvements in its Pharmaceuticals Benefits Scheme (PBS) procedures – including establishment of an independent process to review determinations of product listings – that will enhance transparency and accountability in the operation of the PBS.”) Serious health issues have been raised over US trade agreements, including the pricing of AIDS drugs, and the attempt to use trade agreements to force significant changes in domestic health policy in a very undemocratic and non-transparent fashion. In the Senate version of the Medicare Modernization Act of 2003, a study of the health impact of pharmaceutical trade policy was to be undertaken by the IOM. Prescription Drug and Medicare Improvement Act of 2003 (S.1), § 801. The version passed by the Congress placed the study in the hands of the ‘President’s designees,’ meaning USTR. Medicare Prescription Drug Improvement and Modernization Act of 2003 (H.R. 1), §1123, Pub. L. 108-173 (Dec. 8, 2003). Moving this study to the USTR places the fox in charge of the henhouse.

<sup>25</sup> Congressional Budget Office, *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998): xiii (“Various studies have found that generic entry has little effect on the prices of brand-name drugs...the impact of generic entry on brand-name prices may vary considerably among different types of purchasers.”). For an earlier review, see F.M. Scherer, “Pricing, Profits, and Technological Progress in the Pharmaceutical Industry,” *Journal of Economic Perspectives* 7, no. 3 (Summer 1993) 97-115, at 101. Of course, these studies must be read with the proviso that a complete and accurate pricing dataset was not available.

<sup>26</sup> Of course we have companies such as IMS Health, which prosper by providing prescription drug sales data to the industry. IMS data is incomplete and not public, but is available only by subscription. The State of West Virginia does not subscribe to IMS due to the high cost. It is certainly not financially available to consumers.

In Medicaid, the answer depends on which state you are talking about, and whether the beneficiary is enrolled in managed care, as each state or managed care contractor may have its own confidential rebate arrangement. Drug companies zealously guard the information on Medicaid rebates, essentially forbidding CMS and state Medicaid agencies from publicly disclosing the pricing data.<sup>27</sup> Some Medicare Part B drugs are reimbursed under a form of internal reference pricing.<sup>28</sup> On January 2005, Part B drugs migrate to a new reimbursement system, based on Average Sales Price.<sup>29</sup> Drug prices in Medicare Parts C and D are negotiated by each private contractor and not collected by CMS. Medicare eligible individuals with employer-provided coverage or Medi-Gap policies occupy their own data silos. The Department of Defense employs at least three pricing systems (TRICARE, the Federal Supply Schedule, and the VA). Only the FSS is publicly available. Drug costs for federal employees are again lost in the maze of FEHBP contractors. Hospitals negotiate their own deals through group purchasing organizations. Most of these prices are confidential by contract or statute. As a result, the government buys the same drug at many different prices on any given day.<sup>30</sup>

Imagine the difficulty of assembling a truly comprehensive pricing database. Even if one obtained the actual net price paid for Lipitor 40mg, many other steps must be taken. The data must be expanded beyond Lipitor to all FDA approved products, in myriad dosages, packages and forms. A comparable time series must be created over several years. Price adjustments must also be made for the level of trade, whether retail, wholesale, or ex-factory. All rebates, discounts and subsidies should be included to arrive at a true net price. The data must be globalized across national boundaries, currencies and purchasing power parity. Finally, the information must be put into the hands of the person making the purchasing decision, at the point of sale.

Fear not, the data does actually exist. We can be confident that someone holds accurate data on the ex-factory net price of each drug. But PhRMA companies are not in the mood for pricing transparency. Pricing opacity enables sellers to price discriminate on a global basis, a foundation of PhRMA member profitability.

### **III Is Revolution In The Air?**

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<sup>27</sup> See 42 U.S.C. § 1396r-8(b)(3)(D) (federal law which prohibits disclosure “in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler” in the Medicaid drug rebates) and W.V. Stat. § 9-5-15 (exempting this information from all State disclosure laws).

<sup>28</sup> H.G. Yacker, Congressional Research Service, *Outpatient Prescription Drugs: Acquisition and Reimbursement Policies Under Selected Federal Programs* (Aug 9, 1999): 6.

<sup>29</sup> Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. 108-173, § 303.

<sup>30</sup> The drug industry eagerly defends price discrimination as necessary to support R&D. The Senate Medicare Bill proposed a GAO study on ‘Ramsey pricing,’ which is the ability of price discrimination to efficiently extract consumer surplus. Prescription Drug and Medicare Improvement Act of 2003 (S.1), § 621(a)(3).

- **International Transparency: Imports from Canada**

While conflicts of interest and information disparities flourish, some movement towards pricing transparency can be seen. The provocateurs of this movement were American tourists who depleted their supply of a long-term medication whilst on vacation and refilled the prescription in Canada. Significantly lower prices in Canada encouraged consumer arbitrage of pharmaceuticals.

The Internet dramatically altered the potential for pharmaceutical arbitrage. The transaction cost of importing a prescription from Canada dropped to a small fraction of the arbitrage savings. Many Canadian websites began to compete for American consumers. The media devoted increasing attention to the phenomenon from 1999 onward, raising awareness amongst consumers that arbitrage was an option. A large and growing portion of the most valuable market for patented pharmaceutical medications is now only a click away from lower prices. Congress twice passed drug importation laws which still await a green light from the Secretary of HHS.<sup>31</sup> With Washington in gridlock, states and municipalities are joining the fray, establishing popular drug import programs of dubious legality.<sup>32</sup> Other states are considering reference pricing systems to take advantage of the newly-exposed pricing differentials.

Whatever the fate of the current crop of drug importation bills in Congress, the fact that prescription drugs are much cheaper abroad is now understood by most Americans. Consumers are unlikely to return to their former status as blind price-takers. When highly differentiated prices become observable and comparable at a reasonable information cost, arbitrage pressure will result.<sup>33</sup>

- **Domestic Transparency: The Medicare Website**

The Medicare Modernization Act of 2003 ushers in a new era of domestic price comparison websites, sanctioned by DHHS.<sup>34</sup> Price competition at this level will increase the pressure for transparency in the wholesale and government markets. PhRMA achieved a Pyrrhic victory in enacting the Part D “non-interference” rule,<sup>35</sup> but more notable have been the demands for its repeal, calling for CMS to use its market

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<sup>31</sup> Medicare Prescription Drug Improvement and Modernization Act of 2003, § 1121 (codified at 21 U.S.C. § 804); Medicine Equity and Drug Safety Act of 2000, Pub. L. 106-387, 114 Stat. 1549A-35.

<sup>32</sup> See, e.g., the Illinois report recommending importation. R. Kamath & S. McKibbin, Office of Special Advocate for Prescription Drugs, State of Illinois, *Report on Feasibility of Employees and Retirees Safely and Effectively Purchasing Prescription Drugs from Canadian Pharmacies* (2003).

<sup>33</sup> It is important to limit cross-border price comparisons to high-income OECD countries. For example, it would be inappropriate to compare the US prices for anti-retroviral drugs for AIDS with the charitable prices achieved for distribution in sub-Saharan Africa, as it would undermine a pressing global health effort.

<sup>34</sup> Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. 108-173, § 101, (codified at § 1860D-31(d)(3) of the Social Security Act). The HHS website may be found at: <http://pricecomparison.medicare.gov>. The clickwrap license to the website forbids any collection of data from the website, other than 3 copies for personal use.

<sup>35</sup> Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, § 301 (codified at § 1808(c)(1)(C) of the Social Security Act).

power to negotiate prices. It is but a short step from oligopsony to MedPAC-style price controls.

#### **IV Transparency: The Prescription For Avoiding Price Controls**

PhRMA's fingers may be in the dike, but a sea change is coming in pharmaceutical pricing. The open question is which type of change. For all other major sectors of Medicare, reimbursement began at market prices but eventually succumbed to prices set by government. If PhRMA is to avoid this destiny, it will need to articulate clear reasons why drugs are different from services rendered by physicians, hospitals and clinical labs. If innovation is the defense, then accurate and detailed data must be made public to support the argument.

The industry should embrace transparency to avoid US price controls. Transparency may be the continued price of admission to the pharmaceutical patent system and government reimbursement. Transparency also bears fruit for both PhRMA and health policy.

The first benefit of transparency will be the prevention and treatment of conflicts of interest, which might obviate the need for more intrusive regulatory schemes. The following pharmaceutical data should be publicly disclosed:

- All direct and indirect remuneration from drug companies and their agents to prescribers, PBMs, patient advocacy groups, biomedical and health policy researchers, and scientific administrators such as the NIH.

The second benefit of transparency will be the creation of proper tools for policy evaluation, particularly for evidence-based medicine and reimbursing for value rather than cost. This requires the disclosure to policymakers and the independent research community of the following pharmaceutical data:

- All safety, efficacy and economic evaluation data.
- Drug company financial information, including R&D, P&L, and pricing, audited by a specialized government agency which has access to all state and federal information for comparison, including HHS, DoD, Treasury and the SEC.

The third benefit of transparency will be restoring the pharmaceutical market to a closer approximation of the neo-classical free market ideal. Instead of assuming perfect information, let's improve the quality of information.

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Complying with these disclosures may be difficult for PhRMA companies, given their culture and history; harsher still may be the bitter pill of price controls, should they fail to embrace transparency.